



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,346	07/24/2001	Jian Ni	PF199D2	4955

22195 7590 02/21/2003
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/911,346	Applicant(s) Ni et al.
Examiner Prema Mertz	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 18, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4) Claim(s) 1-132 is/are pending in the application.

4a) Of the above, claim(s) 21-28, 53-60, 84-91, 116-123, and 128-132 is/are withdrawn from consideration.

5) Claim(s) 1-17, 29-49, and 61-64 is/are allowed.

6) Claim(s) 18-20, 50-52, 65-83, 92-115, and 124-127 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

Art Unit: 1646

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I (claims 1-20, 29-52, 61-83, 92-115, and 124-127) in Paper No. 7 (12/18/02) is acknowledged. The traversal is on the ground(s) that the Examiner has made a restriction between Groups I, II and III and Applicants assert that no undue burden would be placed on the Examiner if the three Groups were to be considered in the same application as the searches would be co-extensive. However, a search for the antibody of Group I would not necessarily reveal art for the a method of detecting NKEF C protein in a biological sample using the antibody, classified in class 435, subclass 7.2 (Group II) or a method of treatment by administering the antibody to the NKEF C protein, classified in class 424, subclass 85.1 (Group III).

Furthermore, Applicants arguments are not found persuasive because the searches for the three Groups would not overlap, the inventions being classified in different classes and subclasses. Applicants are directed to MPEP.. 808.02 which states that "Where the related inventions as claimed are shown to be distinct and under the criteria of MPEP.. 806.05 (c-I), the examiner in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: 1) Separate classification thereof." In the instant case, Group I is classified in class 530, subclass 387.9, Group II is classified in class 435, subclass 7.2 and Group III is classified in class 424, subclass 85.1.

The test for propriety of restriction is not whether the inventions are related but rather whether they are distinct and whether it would impose a burden on the examiner to search and

Art Unit: 1646

examine multiple inventions in a single invention. Since Group I and Groups II-III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the antibody of invention I as claimed can be used in a completely unrelated process of immunochromatography, to purify the NKEF C protein.

Therefore, contrary to Applicants arguments, a search of the antibody claims of the instant invention would not necessarily provide information regarding the method of because a search of the literature for the polypeptide, would not be expected to reveal art for the polynucleotide encoding the polypeptide, which searches are extensive requiring separate searches which would be unduly burdensome.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP.. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP.. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

The Groups as delineated in the restriction requirement (Paper No. 6, 11/8/02) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

Art Unit: 1646

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-28, 53-60, 84-91, 116-123, 128-132 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Furthermore, Applicants request rejoinder of the subject matter of Groups II and III with that of Group I (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995)), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product which was free of the prior art. However, only if the product claims of Group I are found allowable, the subject matter of Group II and III will be rejoined with the product claims of Group I, if the process claims are of the same scope as the allowable product claims.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite "antibodies to natural killer cell enhancing factor C".

Claim Rejections - 35 USC § 101

3. 35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 65-83, 124-127 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claims embrace an antibody as it occurs *in vivo* in the immunized animal. However, since it would that applicants do not intend to claim a naturally

Art Unit: 1646

occurring product, such as antibodies in the host, amending the claims to require the hand-of-man would obviate this rejection.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65-83, 92-115, 124-127 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not provide a repeatable method for obtaining ATCC Deposit No. 97157 and it does not appear to be a readily available material. The ATCC 97157 deposit in full compliance with 37 CFR §§ 1.803-1.809 would satisfy the requirements of 35 USC §112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make

Art Unit: 1646

such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Claims 66-91, 94-115, and 125-127 are rejected under 35 U.S.C. 112, first paragraph, insofar as they depend on claims 65, 92-93, 124 for the ATCC Deposit No.

Claim Rejections - 35 USC § 112, second paragraph

5. Claims 18-20, 50-52, 81-83 and 113-115 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18-20, 50-52, 81-83 and 113-115 are drawn to a hybridoma that produces monoclonal antibodies to the protein of amino acid sequence set forth in SEQ ID NO:2. It is suggested that Applicants amend these claims to depend on claims 11, 35, 67 and 98 (drawn to monoclonal antibodies) respectively, rather than on the independent claims they depend from, since only hybridomas produce monoclonal antibodies.

Conclusion

Claims 1-17, 29-49, 61-64, are allowable.

Art Unit: 1646

Claims 18-20, 50-52, 65-83, 92-115, and 124-127 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 17, 2003